UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/952,368	11/17/97	PHIPPS J	ARC2426CIP

EXAMINER	
THOMPSON, M	
ART UNIT	PAPER NUMBER
3763	12

DATE MAILED: 06/19/01

022921 QM32/0619
ALZA CORPORATION
P O BOX 7210
INTELLECTUAL PROPERTY DEPARTMENT
MOUNTAIN VIEW CA 94039-7210

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	08/952,368	PHIPPS ET AL.	
	Examiner	Art Unit	
	Michael M. Thompson	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☒ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 2 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear to the Examiner how stability relates to the efficiency. The real question is 'What about the Efficiency is stable?' when considering Efficiency vs. Current Density. Please note, the Examiner has **not** rejected claims 3-5, 16, 17, and 21-23 and the language "at least about," however, the Examiner would like to notify Applicant that the court has held that claims reciting "*at least* about" were invalid for indefiniteness where there was close prior art and there was nothing in the specification, prosecution history, or the prior art to provide any indication as to what range of specific activity is covered by the term "about." Amen *v. Chugai Pharmaceutical Co. Ltd.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991). In the instant Application Applicant has supplied the current density level for human skin in the range of "about 40 to 100 mu.A/cm.sup.2" in the specification on page 11. Therefore, all values of current density that fall within this range are considered a "critical density" value. Furthermore, since it would be illogical for the Examiner to convert the "critical density" range into the appropriate range values for the frequency and/or pulsing frequency, duty cycle, periodic current waveform (all inherent in these values related to the properties of current) it is the Examiner's position that all values of frequency and/or pulsing frequency, duty cycle, periodic

current waveform are simply different forms of representation within the "critical density" range identified above.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-10 and 12-25 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Tapper ('334) and/or Haak et al.. Tapper and Haak et al. teach an electrotransport device for in vivo delivery of a charged agent through a body surface having, *inter alia*, a source of electrical power, a current controller adapted to

provide a pulsing DC current, (provided by battery in the case of Haak) that is certainly capable of being delivered at various current density levels for any period of time. Please note in Tapper the abstract states, "A method and apparatus for electrical dosimetry control in the application of electric currents to the human body, dosage being determined by the product of time and electrical current, wherein electrical current magnitude and/or time may be selectively varied ....during an administration procedure..." In column 1, lines 28-36, Tapper clearly states that "electric treatments" include DC current. The device has a controller that alters the properties of the current to vary agent delivery rate. These properties are inherent within a DC current. In column 2, lines 56-68 Tapper further states that both the magnitude of the current and frequency are selectively varied. Haak et al. is replete with examples of battery power, control circuitry, waveforms etc., therapeutic drugs (fentanyl), to include varying the current density (col. 14), and administering mixtures of drug (i.e. competitive species).

7. In the alternative, if Applicant disagrees with the statements above with respect to the inherency of the interchangeable nature of frequency and/or pulsing frequency, duty cycle, periodic current waveform being inherent in the properties of current, then it is the Examiner's position that they are indeed obvious. This interpretation of the properties of current further effects Applicant's claims that vary the agent delivery rate. In both instances it is the Examiner's position that these "properties" of current and/or its density (i.e. frequency and/or pulsing frequency, duty cycle, periodic current waveform) are in the least obvious if not inherently relate mathematically and are within the "critical density level" range indicated in Applicant's specification. Therefore, the Examiner contends that values such as current and/or current density that are taught by Tapper to be "varied during an administration procedure" will

obviously if not inherently change the "properties" of current to reflect Applicant's claimed values and/or ranges. In conclusion, Tapper clearly states that the current can "selectively" vary the magnitude of current and frequency which obviously if not inherently meets the limitations of Applicant's claims. (column 2, lines 56-68) With respect to Haak et al. the Examiner would argue that several of the major issues above also apply to the Haak et al. patent of record when applying obviousness.

8. Claims 3-6, 12-13, 17-19, and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tapper ('334) in view of Sorenson et al. (WO 91/15258) and/or Haak et al. It is the Examiner's position that Tapper teaches all of the limitations of the claims 1-10 and 12-25, however, Sorenson is provided to show teaching of DC current being used between the ranges of about 40-100 mu.A, various therapeutic agents for delivery, and the ability for variation in time. While the Examiner maintains that Tapper's broad variation in current, frequency, and time are sufficient to anticipate or render obvious Applicant's claims, Sorenson is provided to show these variations in the prior art since it is well known in the art of electrotransport delivery to vary these magnitudes to include varying time for reasons such as efficiency of transport and/or comfort to the patient. Please note that Applicant is seeking patentability for an electrotransport device which may be characterized in that it is capable of producing and performing at these current density, frequency and/or pulsing frequency, duty cycle, and periodic current waveform levels. In the least, Haak et al teaches these values within the current density range (col. 14) to include the "properties" of current indicated above.

9. Claims 11 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tapper in view of Haak et al.. Tapper teaches all of the limitations of the claim except for explicitly

indicating the introduction of competitive specie to the donor reservoir. Haak et al. teaches the device substantially as claimed (specifically Column 6, lines 61-68), he further states that a therapeutic "system" can be designed to transdermally deliver the therapeutic agent. This is construed by the Examiner to be an example of introducing competitive specie/s to the donor reservoir. One example might be two drugs that are similar in nature and may effect pain receptors. It would have been obvious to one of ordinary skill in the art, at the time of invention to use mixtures of drugs as the therapeutic agent that may be competitive in nature.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contacts

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Michael Thompson whose telephone number is (703) 305-1619. The Examiner can normally be reached on Monday through Friday from 9 am to 5 PM.

Any questions pertaining to informal matters such as the status of a case, missing portions of an Office Action, references, filing, paper matching, etc., should be directed to the Examiner's Legal Instruments Examiner (LIE), Rosalind Smith, at (703) 305-2440.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Primary, AnhTuan Nguyen, can be reached on (703) 308-2154. The fax phone number for the organization where this application or proceeding is assigned is (703) 306-4520.

Michael M. Thompson

Patent Examiner

ANHTUAN T. NGUYEN
PRIMARY EXAMINER
6/15/01

MT

June 15, 2001